

REMARKS

Claims 7-10, 14 and 15 stand finally rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner maintains the position that the term “at least about” does not define specific range limitations, rendering the claims indefinite. Applicants disagree.

The terms “about,” “at least” and “at least about” are well accepted claim language, the intent and scope of which is easily and readily determinable by the skilled practitioner. Indeed, a search of U.S. patents available on www.uspto.gov showed that the term “at least about” is found in the claims of 70,233 issued U.S. patents, see, e.g., U.S. Patent No. 7,357,956.

The scope of e.g., claim 7, which requires that the film of claim 1 comprise at least about 18% dry wt (based on the wt of the final formulated film), is not vague and indefinite. Withdrawal of the Section 112, second paragraph, rejection is requested.

Claims 1-9 and 14-20 under 35 U.S.C. § 103(a) as being unpatentable over Majeti (U.S. Patent No. 5,599,554) in view of Kulkarni et al. (WO 2004/096174 A1). Applicants disagree.

Applicants have discovered that actives having low solubility levels, i.e., actives having solubility levels of less than about 1g/4mL at room temperature can be incorporated into a dissolvable film and delivered in an amount effective to impart a desired action.

Majeti discloses a transdermal or transmucosal administered composition containing nicotine or a combination of nicotine and caffeine. The patch, also alternatively referred to as a film, comprises a backing layer and an adhesive or bioadhesive/mucosal adhesive layer. There is no disclosure or suggestion of administering any active, let alone actives that are not very soluble, using a dissolvable film as disclosed and claimed by applicants.

While Kulkarni discloses dissolvable films, it is silent as to whether actives having low levels of solubility can be incorporated into a dissolvable film at levels where they exert a desired effect when administered. There is no disclosure that would suggest that actives, such as caffeine, could be delivered using the dissolvable film of Kulkarni.

The invention of claims 1-9 and 14-20 would not have been obvious to one skilled in the art from the combined disclosures of Majeti and Kulkarni. Withdrawal is requested.

Claims 1-20 are finally rejected under 35 U.S.C. § 103(a) as being unpatentable Ballard (U.S. Publication No. 2005/0013847) in view of Kulkarni et al. (WO 2004/096174 A1).

Ballard discloses gel films formed of structured alginate used to deliver actives for oral car to the oral cavity. Ballard does not teach or even suggest that the active can be solubilized or dispersed in an aqueous environment and mixed with film forming agents to form a dissolvable film. Kulkarni adds nothing to the disclosure of Ballard to render the claimed invention obvious. While Ballard and Kulkarni discloses films useful in administering actives, there is no disclose or suggestion that actives having low levels of solubility can be incorporated into a dissolvable film at levels where a desired effect is obtained following administration. There is no disclosure that would suggest that actives, such as caffeine, could be successfully delivered using the film of Ballard or Kulkarni so as the render the claimed invention obvious.

The invention of claims 1-20 would not have been obvious to one skilled in the art from the combined disclosures of Ballard and Kulkarni. Withdrawal is requested.

Respectfully submitted,

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